

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: _____.

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen,
518057, P. R. China

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Contact Person:

Zhai Pei

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: September 27, 2010

2. Device Name:

DC-7 Diagnostic Ultrasound System

DC-3/DC-3T Diagnostic Ultrasound System

Classification

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Device Description:

The DC-3/DC-3T Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, Color mode, PW mode, CW mode, Power mode, DirPower

mode or the combined mode (i.e. B/M Mode). This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array with a frequency range of approximately 2.0 MHz to 12.0 MHz.

4. Intended Use:

The DC-3/DC-3T diagnostic ultrasound system is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetrics, abdominal, pediatric, small parts(breast, thyroid, testicle, etc), neonatal cephalic, transcranial, cardiac, transvaginal, transrectal,peripheral vascular, intraoperative, urology, orthopedics, and musculoskeletal (conventional and superficial) exams.

5. Comparison with Predicate Device:

DC-3/DC-3T Diagnostic Ultrasound System is comparable with and substantially equivalent to the Mindray DC-7(K101041), Mindray DC-3/DC-3T (K091941) and Mindray M5(K102991) Diagnostic Ultrasound System. They have the same technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes as the predicate device.

6. Non-clinical Tests:

DC-3/DC-3T Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards. This device has been designed to meet the following standards: UD 2, UD 3,IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-37 ,IEC 60601-1-4 ,ISO 10993-1 and IEC 62304.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the DC-3/DC-3T Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
GREAT NECK NY 11021

NOV - 3 2010

Re: K102865

Trade/Device Name: DC-3/DC-3T Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, IYN, and ITX
Dated: September 30, 2010
Received: September 30, 2010

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DC-3/DC-3T Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

3C5A
6CV1
7L4A
7L6
10L4

6C2
6LE7
6LB7
3C1
2P2

7L5
7LT4
D6-2

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

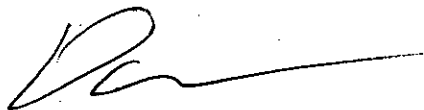
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

K102865

Indications for Use

NOV - 3 2010

510(k) Number (if known):

Device Name: DC-3/DC-3T Diagnostic Ultrasound System

Indications For Use:


The DC-3/DC-3T diagnostic ultrasound system is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetrics, abdominal, pediatric, small parts (breast, thyroid, testicle, etc), neonatal cephalic, transcranial, cardiac, transvaginal, transrectal, peripheral vascular, intraoperative, urology, orthopedics, and musculoskeletal (conventional and superficial) exams.

Prescription Use ☒
 (Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use ☐
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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0029

Diagnostic Ultrasound Indications for Use Form

System: DC-3/DC-3T Diagnostic Ultrasound System
 Transducer: N/A
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1,2,3,4,5,6,7
	Abdominal	P	P	P	P	P	P	P	Note 1,2,3,4,5,6,7
	Intraoperative (specify)*	P	P	P		P	P	P	Note 2,3,4,5,6
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1,2,3,4,5,6,7
	Small organ(specify)**	P	P	P		P	P	P	Note 2,3,4,5,6
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1,2,3,4,5,6
	Adult Cephalic	P	P	P	P	P	P	P	Note 1,2,3,5,6
	Trans-rectal	P	P	P		P	P	P	Note 2,3,4,5,6
	Trans-vaginal	P	P	P		P	P	P	Note 2,3,5,6
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal Conventional	P	P	P		P	P	P	Note 2,3,4,5,6
	Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2,3,4,5,6
	Intravascular								
	Other (specify)***	P	P	P		P	P	P	Note 1,2,3,4,5,6
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	Note 1,2,3,4,5,6
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1,2,3,4,5,6
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P	Note 1,2,3,4,5,6
	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Note4: iBeam

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D

Prescription USE (Per 21 CFR 801.109)

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K102865

0030

Diagnostic Ultrasound Indications for Use Form

System: DC-3/DC-3T Diagnostic Ultrasound System
 Transducer: 3C5A
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 3, 5, 6
	Abdominal	P	P	P		P	P	P	Note 1, 2, 3, 5, 6
	Intraoperative (specify)*								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1, 2, 3, 5, 6
	Small organ(specify)**								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intravascular								
	Other (specify)***	P	P	P		P	P	P	Note 1, 2, 3, 5, 6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P	Note 1, 2, 3, 5, 6
	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

Note 5: Biopsy Guidance

Note 6: Free X-ray M

Note 7: 4D

Prescription USE (Per 21 CFR 801.109)

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K102865

0031

Diagnostic Ultrasound Indications for Use Form

System: DC-3/DC-3T Diagnostic Ultrasound System
 Transducer: 6CV1
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 2, 3, 5, 6
	Abdominal								
	Intraoperative (specify)*								
	Intraoperative (Neuro)								
	Laparoscopy								
	Pediatric								
	Small organ (specify)**								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	Note 2, 3, 5, 6
	Trans-vaginal	P	P	P		P	P	P	Note 2, 3, 5, 6
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal Conventional								
	Musculo-skeletal Superficial								
Cardiac	Intravascular								
	Other (specify)***	P	P	P		P	P	P	Note 2, 3, 5, 6
	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
Peripheral Vascular	Trans-esoph. (Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScope

Note 4: iBeam

Note 5: Biopsy Guidance

Note 6: Free Xros M

Note 7: 4D

Prescription USE (Per 21 CFR 801.109)

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K102865

0032

Mindray Co. Ltd. - DC-3/DC-3T Diagnostic Ultrasound System

Diagnostic Ultrasound Indications for Use Form

System: DC-3/DC-3T Diagnostic Ultrasound System

Transducer: 7L4A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 2,3,4,5,6
	Intraoperative (specify)*								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 2,3,4,5,6
	Small organ(specify)**	P	P	P		P	P	P	Note 2,3,4,5,6
	Neonatal Cephalic	P	P	P		P	P	P	Note 2,3,4,5,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal Conventional	P	P	P		P	P	P	Note 2,3,4,5,6
	Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2,3,4,5,6
Cardiac	Intravascular								
	Other (specify)***								
	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
Peripheral Vascular	Intra-Cardiac								
	Peripheral Vascular	P	P	P		P	P	P	Note 2,3,4,5,6
	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Note4: iBeam

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D

Prescription USE (Per 21 CFR 801.109)

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0033

Mindray Co. Ltd. - DC-3/DC-3T Diagnostic Ultrasound System

Diagnostic Ultrasound Indications for Use Form

System: DC-3/DC-3T Diagnostic Ultrasound System
 Transducer: 7L6
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 2,3,4,5,6
	Intraoperative (specify)*								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 2,3,4,5,6
	Small organ(specify)**	P	P	P		P	P	P	Note 2,3,4,5,6
	Neonatal Cephalic	P	P	P		P	P	P	Note 2,3,4,5,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal Conventional	P	P	P		P	P	P	Note 2,3,4,5,6
	Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2,3,4,5,6
	Intravascular								
	Other (specify)***								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P	Note 2,3,4,5,6
	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Note4: iBeam

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D

Prescription USE (Per 21 CFR 801.109)

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0034

Diagnostic Ultrasound Indications for Use Form

System: DC-3/DC-3T Diagnostic Ultrasound System
 Transducer: 10L4
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 2,3,4,5,6
	Intraoperative (specify)*								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 2,3,4,5,6
	Small organ(specify)**	P	P	P		P	P	P	Note 2,3,4,5,6
	Neonatal Cephalic	P	P	P		P	P	P	Note 2,3,4,5,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal Conventional	P	P	P		P	P	P	Note 2,3,4,5,6
	Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2,3,4,5,6
	Intravascular								
	Other (specify)***								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
Peripheral Vascular	Intra-Cardiac								
	Peripheral Vascular	P	P	P		P	P	P	Note 2,3,4,5,6
	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E.

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScan

Note4: iBeam

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D

Prescription USE (Per 21 CFR 801.109)

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 Office of In Vitro Diagnostic Device Evaluation and Safety

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0035

Mindray Co. Ltd. - DC-3/DC-3T Diagnostic Ultrasound System

Diagnostic Ultrasound Indications for Use Form

System: DC-3/DC-3T Diagnostic Ultrasound System
 Transducer: 6C2
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 2, 3,5,6
	Intraoperative (specify)*								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 2, 3,5,6
	Small organ(specify)**								
	Neonatal Cephalic	P	P	P		P	P	P	Note 2, 3,5,6
	Adult Cephalic	P	P	P		P	P	P	Note 2, 3,5,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal Conventional								
	Musculo-skeletal Superficial								
Cardiac	Intravascular								
	Other (specify)***	P	P	P		P	P	P	Note 2, 3,5,6
	Cardiac Adult	P	P	P		P	P	P	Note 2, 3,5,6
	Cardiac Pediatric	P	P	P		P	P	P	Note 2, 3,5,6
	Intravascular (Cardiac)								
Peripheral Vascular	Trans-esoph.(Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

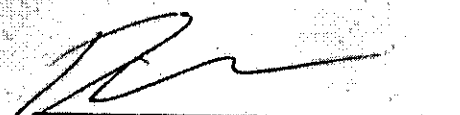
Note 3: iScape

Note4: iBeam

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D


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Prescription USE (Per 21 CFR 801.109)

0036

Mindray Co. Ltd. - DC-3/DC-3T Diagnostic Ultrasound System

Diagnostic Ultrasound Indications for Use Form

System:

DC-3/DC-3T Diagnostic Ultrasound System

Transducer:

6LE7

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 2,3,4,5,6
	Abdominal								
	Intraoperative (specify)*								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small organ(specify)**								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	Note 2,3,4,5,6
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intravascular								
	Other (specify)***	P	P	P		P	P	P	Note 2,3,4,5,6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D


Note 3: iScape

Note4: iBeam

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D


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Office of In Vitro Diagnostic Device Evaluation and Safety

510K

1102865

Prescription USE (Per 21 CFR 801.109)

0037

Diagnostic Ultrasound Indications for Use Form

System:

DC-3/DC-3T Diagnostic Ultrasound System

Transducer:

6LB7

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (specify)*								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small organ(specify)**								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	Note 2,3,4,5,6
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph (non-Card.)								
	Musculo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intravascular								
	Other (specify)***	P	P	P		P	P	P	Note 2,3,4,5,6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

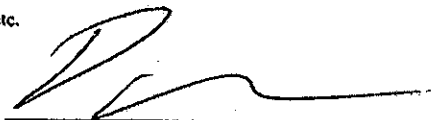
Note 3: iScape

Note 4: iBeam

Note 5: Biopsy Guidance

Note 6: Free Xros M

Note 7: 4D


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 Office of In Vitro Diagnostic Device Evaluation and Safety
 510K K102865

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: DC-3/DC-3T Diagnostic Ultrasound System
 Transducer: 3CI
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2,3,5,6
	Intraoperative (specify)*								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,3,5,6
	Small organ(specify)**								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intravascular								
	Other (specify)***								
Cardiac	Cardiac Adult	P	P	P		P	P	P	Note 1,2,3,5,6
	Cardiac Pediatric	P	P	P		P	P	P	Note 1,2,3,5,6
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes; etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Note4: iBeam

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D

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K102865

Prescription USE (Per 21 CFR 801.109)

Mindray Co. Ltd. - DC-3/DC-3T Diagnostic Ultrasound System

Diagnostic Ultrasound Indications for Use Form

System: DC-3/DC-3T Diagnostic Ultrasound System
 Transducer: 2P2
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P	P	P	P	P	Note 1, 2,5,6
	Intraoperative (specify)*								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1, 2,5,6
	Small organ(specify)**								
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1, 2,5,6
	Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2,5,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intravascular								
	Other (specify)***								
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	Note 1, 2,5,6
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1, 2,5,6
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

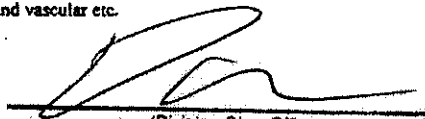
Note 3: iScape

Note4: iBeam

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D



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K102865

Prescription USE (Per 21 CFR 801.109)

0040

Diagnostic Ultrasound Indications for Use Form

System: DC-3/DC-3T Diagnostic Ultrasound System
 Transducer: 7L5
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 2,3,4,5,6
	Intraoperative (specify)*								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 2,3,4,5,6
	Small organ(specify)**	P	P	P		P	P	P	Note 2,3,4,5,6
	Neonatal Cephalic	P	P	P		P	P	P	Note 2,3,4,5,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal Conventional	P	P	P		P	P	P	Note 2,3,4,5,6
	Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2,3,4,5,6
	Intravascular								
	Other (specify)***								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
Peripheral Vascular	Intra-Cardiac								
	Peripheral Vascular	P	P	P		P	P	P	Note 2,3,4,5,6
	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW+Color+B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

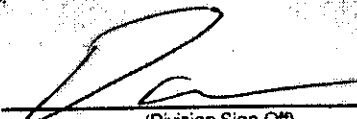
Note 3: iScape

Note4: iBeam

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D


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K102805

Prescription USE (Per 21 CFR 801.109)

Mindray Co. Ltd. - DC-3/DC-3T Diagnostic Ultrasound System

Diagnostic Ultrasound Indications for Use Form

System:

DC-3/DC-3T Diagnostic Ultrasound System

Transducer:

7LT4

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 2,3,4,5,6
	Intraoperative (specify)*	P	P	P		P	P	P	Note 2,3,4,5,6
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 2,3,4,5,6
	Small organ(specify)**	P	P	P		P	P	P	Note 2,3,4,5,6
	Neonatal Cephalic	P	P	P		P	P	P	Note 2,3,4,5,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal Conventional	P	P	P		P	P	P	Note 2,3,4,5,6
	Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2,3,4,5,6
	Intravascular								
	Other (specify)***								
Cardiac	Cardiac Adult	P	P	P		P	P	P	Note 2,3,4,5,6
	Cardiac Pediatric	P	P	P		P	P	P	Note 2,3,4,5,6
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P	Note 2,3,4,5,6
	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Note4: iBeam

Note5: Biopsy Guidance

Note6: Free Xios M

Note7: 4D

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Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: DC-3/DC-3T Diagnostic Ultrasound System
 Transducer: D6-2
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 3, 6, 7
	Abdominal	P	P	P		P	P	P	Note 1, 2, 3, 6, 7
	Intraoperative (specify)*								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1, 2, 3, 6, 7
	Small organ (specify)**								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intravascular								
	Other (specify)***								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
Peripheral Vascular	Intra-Cardiac								
	Peripheral Vascular								
	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B; PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D


Note 3: iScape

Note 4: iBeam

Note 5: Biopsy Guidance

Note 6: Free Xros M

Note 7: 4D


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